



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,183	09/25/2003	William T. Donofrio	END 5026	6391

27777 7590 11/13/2006  
PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
----------

LOPEZ, AMADEUS SEBASTIAN

ART UNIT	PAPER NUMBER
----------	--------------

3771

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/671,183	DONOFRIO, WILLIAM T.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amadeus S. Lopez	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/12/04</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 6, 7, 15, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Hickie (2005/0112325).

As to claim 1 Hickie discloses a conscious sedation system comprising

a) a controller(14) which generates a request for a predetermined response from a patient (paragraph 69) and which analyses at least a response made by the patient to the request to determine a level of sedation of the patient (paragraph 113); and b) a response testing apparatus (256) including: (1) a request assembly (264) which communicates to the patient the request generated by the controller; and (2) a response assembly (266) which senses the response and which communicates the response to the controller, wherein at least one of the request assembly and the response assembly includes a cableless communication device which communicates at least one of the request and the response between the controller and the patient (paragraph 136; states that the controller that communicates with either the request/response assemblies can be set at a remote location and is therefore cableless or wireless).

As to claim 2, Hickle discloses a conscious sedation system, wherein a user and/or the controller determines a delivery schedule of a conscious-sedation drug to the patient based at least in part on the determined level of sedation of the patient (paragraphs 113 and 114).

As to claim 5, discloses conscious sedation system, also including a console, wherein the controller is disposed in the console (10; Fig.1).

As to claim 6, discloses a response testing apparatus for a conscious sedation system comprising: a) a request assembly (264) which communicates to a patient a request generated by a controller (14) of the conscious sedation system for a predetermined response from the patient; and b) a response assembly (266) which senses a response made by the patient to the request and which communicates the response to the controller which analyses at least the response to determine a level of sedation of the patient (paragraph 113), wherein at least one of the request assembly and the response assembly includes a cableless communication device which communicates at least one of the request and the response between the controller and the patient (paragraph 136; states that the controller that communicates with either the request/response assemblies can be set at a remote location and is therefore cableless or wireless).

As to claim 7, discloses a response testing apparatus wherein the request assembly includes a cableless communication device, which communicates the request from the controller to the patient (paragraph 113, 114, 124 and 136; request device can

Art Unit: 3771

take several embodiments such as disclosed, a speaker which provides an audible command for a patient to activate the response switch).

As to claim 15, discloses a response testing apparatus (266) wherein the response assembly includes a cableless communication device, which communicates the response from the patient to the controller (paragraph 112, 113, and 136).

As to claim 18, discloses a response testing apparatus wherein the request assembly includes a cableless communication device, which communicates the request from the controller to the patient, and wherein the response assembly includes a cableless communication device which communicates the response from the patient to the controller (Paragraph 112-114 and 136; if controller were set at a remote location and operated wirelessly, then the wires and cables connecting the controller to the response and request assemblies would inherently be "cableless").

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 4, 8-14, 16, 17, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie in view of Randell et al (6415439)

As to claim 3, Hickie discloses a conscious sedation system with all the limitations of claim 3 with the exception of wherein the cableless communication device includes a transmitter and a receiver in cableless communication with the transmitter, and wherein the cableless communication device imposes a unique identifier on at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to crosstalk from other transmitters. Randell et al disclose a protocol for a wireless control system wherein the cableless communication device includes a transmitter (86) and a receiver (87) in cableless communication with the transmitter, and wherein the cableless communication device imposes a unique identifier (112) on at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to crosstalk from other transmitters (Col. 18, lines 46-62). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation system of Hickie to have a transmitter and receiver wherein the device imposes a unique identifier on at least one of the transmitter and the receiver because the use of a transmitter and receiver is well known in the wireless control system art and "the identifier allows the controller to distinguish among several devices of the same genus that respond to the same link acquisition message (cross talk)." Further it is inherent that a wireless system

Art Unit: 3771

such as Hickle has a receiver and transmitter of some sort although it is not explicitly expressed.

As to claim 4, Hickle disclose a conscious sedation system with all the limitations of claim 4 with the exception of wherein the unique identifier is manually-triggered, or is automatically proximity-triggered when the transmitter and the receiver are brought into proximity to each other, or requires both manual and proximity triggering (Col. 4, lines 1-7, which expresses that the identifier can be manually triggered by the protocol handler as taught by Randell et al. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickle to include a manually or automatically triggered identifier since it is well known in the art as taught by Randell et al to utilize identifiers to prevent crosstalk between different devices.

As to claim 8, Hickle disclose a response testing apparatus with all the limitations of claim 8 with the exception of wherein the cableless communication device includes an RF transmitter (86) and includes an RF receiver (87) in wireless communication with the RF transmitter and disposed proximate the patient as taught by Randell et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickle to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 9, Hickle disclose a testing apparatus with all the limitations of claim 9 with the exception of wherein the request assembly verifies that the request was

received by the RF receiver. Randell et al disclose a protocol for a wireless control system that utilizes an RF receiver for receiving signals from a transmitter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickie to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 10, Hickie discloses a response testing apparatus wherein the request assembly includes a battery-operated portion, and wherein the request assembly includes a battery-operated portion (paragraph 160).

As to claim 11, Hickie discloses a response testing apparatus (266) wherein the request assembly includes a speaker (paragraph 124), which is activated to produce an audible request to the patient (paragraph 124). Hickie does not disclose the use of an RF receiver to activate the speaker. Randell et al disclose a protocol for a wireless control system that utilizes an RF receiver to receive signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickie to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 12, Hickie discloses a response testing apparatus (266) wherein the speaker is an earphone disposable proximate an ear of the patient (Fig. 16).

As to claim 13, Hickie discloses a response testing apparatus wherein the request assembly (264) includes a vibrator that is activated to produce a tactile



Art Unit: 3771

response to the patient (paragraph 121). Hickle does not disclose an RF receiver used to activate the vibrator. Randell et al disclose a protocol for a wireless control system that utilizes an RF receiver. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickle to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 14, Hickle discloses a response testing apparatus wherein the vibrator is disposed in a handpiece (paragraph 121), and wherein the handpiece is disposable proximate a hand of the patient (paragraph 121; further it is inherent that a handpiece would be proximate a patient's hand).

As to claim 16, Hickle discloses a response testing apparatus wherein the cableless communication device includes a transmitter (in the form of a speaker or vibrator in a handpiece) disposed proximate the patient and includes a receiver (system inherently has a receiver that receives signals sent from transmitter that is analyzed by the controller to determine level of sedation) in wireless communication with the transmitter (paragraph 136; if controller were set at a remote location and operated wirelessly, then the wires and cables connecting the controller to the response and request assemblies would inherently be "cableless"). Hickle disclose a response testing apparatus with all the limitations of claim 16 with the exception of wherein the cableless communication device includes an RF transmitter (86) and includes an RF receiver (87) in wireless communication with the RF transmitter and disposed proximate the patient as taught by Randell et al. It would have been obvious to one of ordinary skill in the art

Art Unit: 3771

at the time the invention was made to modify the wireless sedation apparatus of Hickle to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 17, Hickle discloses a response testing apparatus wherein the response assembly includes a handpiece (Fig. 12A; paragraph 120 and 121) disposable proximate a hand of the patient, wherein the handpiece includes a switch (307), and wherein the response includes the patient activating the switch whereby a signal is sent by a transmitter. Hickle does not disclose that the transmitter is an RF transmitter. Randell et al disclose a protocol for a wireless control system that utilizes an RF transmitter. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickle to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 19, discloses a response testing apparatus for a conscious sedation system comprising: a) a request assembly (264) which communicates to a patient a request generated by a controller of the conscious sedation system for a predetermined response from the patient (paragraph 69); and b) a response assembly (266) which senses a response made by the patient to the request and which communicates the response to the controller which analyses at least the response to determine a level of sedation of the patient (paragraph 113), wherein at least one of the request assembly and the response assembly includes a cableless communication device which communicates at least one of the request and the response between the controller and

Art Unit: 3771

the patient (Paragraph 112-114 and 136; if controller were set at a remote location and operated wirelessly, then the wires and cables connecting the controller to the response and request assemblies would inherently be "cableless"). What Hickle does not disclose is wherein the cableless communication device includes a transmitter and a receiver in cableless communication with the transmitter, and wherein the cableless communication device imposes a unique identifier on at least one of the transmitter and the receiver which prevents the cableless communication device from responding to crosstalk from other transmitters. Randell et al disclose a protocol for a wireless control system wherein the cableless communication device includes a transmitter (86) and a receiver (87) in cableless communication with the transmitter, and wherein the cableless communication device imposes a unique identifier (112) on at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to crosstalk from other transmitters (Col. 18, lines 46-62). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation system of Hickle to have a transmitter and receiver wherein the device imposes a unique identifier on at least one of the transmitter and the receiver because the use of a transmitter and receiver is well known in the wireless control system art and "the identifier allows the controller to distinguish among several devices of the same genus that respond to the same link acquisition message (cross talk)." Further it is inherent that a wireless system such as Hickle has a receiver and transmitter of some sort although it is not explicitly expressed.

As to claim 20, Hickle disclose a conscious sedation system with all the limitations of claim 4 with the exception of wherein the unique identifier is manually-triggered, or is automatically proximity-triggered when the transmitter and the receiver are brought into proximity to each other, or requires both manual and proximity triggering (Col. 4, lines 1-7, which expresses that the identifier can be manually triggered by the protocol handler as taught by Randell et al. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickle to include a manually or automatically triggered identifier since it is well known in the art as taught by Randell et al to utilize identifiers to prevent crosstalk between different devices.

As to claim 21, Hickle disclose a response testing apparatus with all the limitations of claim 21 with the exception of wherein the cableless communication device includes an RF transmitter (86) and includes an RF receiver (87) in wireless communication with the RF transmitter and disposed proximate the patient as taught by Randell et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation apparatus of Hickle to utilize RF transmitters and receivers because their use is well known in the art as taught by Randell et al in wireless control systems.

As to claim 22, Hickle disclose a response testing apparatus with all the limitations of claim 22 with the exception of wherein the cableless communication device selects the operating frequency of at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to

crosstalk from other transmitters. Randell et al disclose a protocol for a wireless control system wherein the cableless communication device selects the operating frequency of at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to crosstalk from other transmitters (Col. 2, lines 26-42 and Col. 18, lines 46-62). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation system of Hickie to select the operating frequency of at least one of the transmitter and receiver, to minimize cross talk and interference between similar transmitters and receivers in the area as taught by Randell et al.

As to claim 23, Hickie disclose a response testing apparatus with all the limitations of the claim with the exception of wherein the cableless communication device selects a digital code for at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to crosstalk from other transmitters. Randell et al disclose a protocol for a wireless control system wherein the cableless communication device includes a transmitter (86) and a receiver (87) in cableless communication with the transmitter, and wherein the cableless communication device imposes a unique identifier (112; which could be a digital code) on at least one of the transmitter and the receiver, which prevents the cableless communication device from responding to crosstalk from other transmitters (Col. 18, lines 46-62). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation system of Hickie to have a transmitter and receiver wherein the device imposes a unique identifier on at

least one of the transmitter and the receiver because the use of a transmitter and receiver is well known in the wireless control system art and "the identifier allows the controller to distinguish among several devices of the same genus that respond to the same link acquisition message (cross talk)."

As to claim 24, Hickie discloses a response testing apparatus with all the limitations of claim 24 with the exception of including a lockout, which prevents use of the cableless communication device unless the imposition of the unique identifier has been successfully verified. Randell et al disclose a protocol for a wireless control system that includes a lockout, which prevents the use of the cableless communication device unless the imposition of the unique identifier has been verified (Col. 21, line 65 to Col. 22, line 34). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the wireless sedation system of Hickie to include a lockout, which prevents the use of the device unless the imposition of the unique identifier has been verified to ensure that no cross talk or interference occurs during the use of the sedation system, which may be detrimental to the health of the patient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

Art Unit: 3771

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Amadeus S Lopez  
Examiner  
Art Unit 3771  
November 9, 2006

ASL



JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

11/9/06